UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/218,213	12/22/98	SCHUTT E	ALLIA.171CPC

020995 HM12/1116
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EXAMINER	
TRAN,S	
ART UNIT	**PAPER NUMBER**
1615	16

DATE MAILED: 11/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/218,213	Schutt et al.
Examiner	**Group Art Unit**
Susan Tran	1615

☒ Responsive to communication(s) filed on *Sep 15, 2000* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-55* is/are pending in the application.

Of the above, claim(s) *1, 3-5, 13-38, and 40-42* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2, 6-12, 39, and 43-55* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Receipt is acknowledged of applicants' Declaration filed 03/22/99, Verified Statement filed 03/22/99, Corrected Filing Receipt filed 03/22/99, Preliminary Amendment A filed 4/26/99, Information Disclosure Statement filed 05/06/99, Information Disclosure Statement (Supplemental) filed 06/01/99, Extension of Time filed 12/28/99, Amendment B and Statement Establishing Right of Assignee to Take Action filed 02/08/00, Extension of Time and Amendment C filed 09/15/00.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "more than 30% of the average particle volume of the perforated microstructure is permeated by said suspension medium" is not disclosed in the specification.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 6-12, and 39, 43-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al. USPN 6,041,777 ('777), in view of Hanes et al. USPN 5,855,913 ('913).

Faithfull teaches a methods and apparatus for closed-circuit ventilation for pulmonary administration of fluorochemicals agents, bioactive agent, and pharmaceutical agent (column 6, lines 19-47). The closed-circuit ventilation further comprising a nebulizer in the fluid-conducting reservoir, which may be used to introduce aerosols, mists, sprays or to deliver liquid medium, i.e. fluorochemicals to the gas flow path (column 16, lines 27-55). The bioactive agent comprising antibiotics such as penicillins, macolides, quinolines, and tetracyclines; anti-inflammatories; cardiovascular agents; protein; and surfactants (columns 25 and 26).

Faithfull teaches the use of surfactants, however fails to specifically teach phospholipid surfactant as in the claims.

Hanes teaches a pulmonary drug delivery comprising biodegradable particles having density less than about 0.4 g/cm^3, and L-α-phosphatidylcholine dipalmitoyl ("DPPC") as a surfactant (columns 4 and 5). The particles can be in single and double emulsion, phase separation or spray drying (column 6, lines 60-67), and the microspheres or particles used in this

drug can be in different diameter sizes ranging from about 1-1000 μm, and the mean diameter of at least about 5μm (columns 7 and 8). Column 9, lines 15-20 discloses particle having mean aerodynamic diameter size greater than approximately 1 μm. The bioactive agents comprising polysaccharides, antibiotics, peptides or proteins in the aerosol form, and to be administered to the respiratory system (column 10, lines 4-60).

Absent unexpected results, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify Faithfull's pulmonary drug delivery system with the use of phospholipid surfactant in view of the teaching of Hanes to obtain the claimed invention. The reason for this modification is to improve the aerosolization of the particles and to reduce particle agglomeration, thus promote absorption of a drug and increase bioavailability of the drug in the lung.

Regarding claims 52 and 53, it would have been obvious for one of the ordinary skill in the art to, by routine experimentation determine suitable creaming time to achieve a desirable stability because the cited reference teaches the advantageous results obtain from the particular particles size.

Response to Arguments

3. Applicant's arguments filed 09/15/00 have been fully considered but they are not persuasive. The examiner maintains the original rejection and thus, claims 2, 6-12, and 39, 43-51

are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al. USPN 6,041,777 ('777), in view of Hanes et al. USPN 5,855,913 ('913).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Faithfull is silent as to the stability problems. However, applicants' attention is called to column 4, lines 26-52, wherein the prior art teaches that fluorochemicals are the preferred respiratory promoter, and that the delivery systems provide efficacy and stability of the bioactive agent. The burden is shifted to applicants to provide side by side comparisons to distinguish over the applied prior art.

Applicants argue that Hanes provides no guidance to one of ordinary skill in the art seeking to address problems related to suspension stability. Accordingly, applicants' specification page 21, lines 17-20 recites stability as to resist aggregation or flocculation. The examiner relies on the teaching of Hanes in column 4, lines 53-56, wherein particles having diameter size greater than 5μm and rough surface texture to reduce particle agglomeration and improve flowability of the powder. It is the position of the examiner that such language does address the stability desire by applicants.

Applicants argue that Hanes is silent as to the use of the respiratory promoter such as fluorochemical. However, the examiner relies on the teaching of Hanes in column 10, lines 4-56,

wherein variety of therapeutic agents are using such as agent for treatment of asthma, emphysema that can be administered to the respiratory system. It is the position of the examiner that the cited prior art does disclose respiratory agents and thus, the skill artisan in this art would have been motivated to select fluorochemical because it is a well known respiratory promoter in the pharmaceutical art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600